IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' REPLY BRIEF SUPPORTING MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.

I. The Court should exclude Dr. Shull's warning opinions, because he is not qualified and certain of his opinions are irrelevant.

The parties appear to be in agreement that, consistent with the Court's prior rulings, Dr. Shull's general warning opinions should be limited to testimony "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Produc. Liab. Litig.*, 2016 WL 458220, at *3 (S.D. W. Va. Sept. 1, 2016).

The parties, however, disagree as to whether Dr. Shull may testify about special patient populations. Notwithstanding Plaintiffs' argument, this is not a case-specific issue, because Dr. Shull's opinions are set forth in his general report and not a case-specific report. Ethicon's challenge could only be construed as case-specific due to the mere fact that only one plaintiff in this wave of cases has disclosed Dr. Shull as a general causation expert. Consistent with its ruling in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 705 (S.D.W. Va. 2014), the Court should exclude such opinions.

II. The Court should preclude Dr. Shull from testifying that traditional surgical procedures are a safer alternative to Prolift +M, because his opinions are irrelevant.

Plaintiffs argue that Ethicon's challenge to Dr. Shull's opinions about traditional surgical procedures should only be handled in a case-specific motion. Yet, this Court recently refused to consider such a challenge in a case-specific motion on the basis that it is within "the province of a general causation expert—not a specific causation expert." *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017), Ex. C to Doc. 4355.

Plaintiffs do not deny that the law of Pennsylvania—the only state law applicable to this wave of cases with respect to Dr. Shull's opinions—requires a plaintiff to show the existence of "an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered." *Berrier v. Simplicity Mfg.*, 563 F.3d 38, 64 (3d Cir. 2009). Plaintiffs also do not dispute that the traditional surgical procedures that Dr. Shull discusses are not products or designs. Therefore, the Court should exclude these opinions.

III. The Court should preclude Dr. Shull from suggesting that other synthetic mesh devices have fewer complications, because his opinions are irrelevant and/or unreliable.

According to Plaintiffs, the Court denied Ethicon's Wave 1 motion to preclude Dr. Shull from suggesting that a device with a different type of synthetic mesh would be a safer alternative to Prolift +M. In reality, the Court merely denied Ethicon's motion on the basis that the Court did not interpret Dr. Shull's report as providing such an opinion. *See In re: Ethicon*, 2016 WL 458220, at *3 (S.D.W. Va. Sept. 1, 2016). According to the Court: "But the challenged statement was not about the overall balance between safety and efficacy or the appropriateness of an alternative design; Dr. Shull was merely opining on adverse reactions." *Id.*

In Ethicon's Wave 5 brief, Ethicon afforded Plaintiffs the opportunity to clarify whether they, in fact, intend to elicit testimony from Dr. Shull about "the overall balance between safety

and efficacy or the appropriateness of an alternative design." *Id.* Plaintiffs, however, have attempted to dodge this question. Accordingly, consistent with its Wave 1 ruling, the Court should find that Dr. Shull's opinions on this subject are limited to "adverse reactions."

IV. The Court should preclude Dr. Shull from providing design and development opinions, because he is unqualified to do so.

On the one hand, Plaintiffs appear to agree with the Court's Wave 1 ruling that "Dr. Shull has not expressed any opinions about the process of designing a product," *In re: Ethicon*, 2016 WL 4582220, at *3, stating "[f]ine, Plaintiffs agree." Doc. 4554, Pl's Resp. at 8. Yet, in the very next paragraph of their response, Plaintiffs ask the Court to allow Dr. Shull to testify that, "[f]rom a clinical perspective, Ethicon did not exercise due diligence in the design and development of the" devices at issue. *Id.* at 9 (quoting Ex. B to Doc. 4355, Shull Prolift +M Report at 3).

Aside from the fact that their position is self-contradictory, Plaintiffs make no attempt to explain how Dr. Shull has any expertise in addressing due diligence on the part of the manufacturer of medical devices or what reliable methodology he employed to arrive at any such opinion or how he has any expertise in providing "design and development" opinions "from a clinical perspective." Consistent with its decisions in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612-13 (S.D.W. Va. 2013), and *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561-62 (S.D. W. Va. 2014), the Court should exclude such opinions.

V. The Court should not allow Dr. Shull to speculate about the duties of a medical device manufacturer.

A. Research/Testing

Plaintiffs argue that Dr. Shull should be allowed to testify about Ethicon's duty to conduct clinical testing on the basis that Ethicon's own company documents reveal that it was

not performed. To the extent that Dr. Shull intends to testify about Ethicon's internal documents, this is not proper expert testimony. *See Bellew v. Ethicon, Inc.*, 2014 WL 12685965, at *9 (S.D.W. Va. Nov. 20, 2014) ("Whether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct").

Yet, Dr. Shull's statements in his report plainly go beyond factual assertions. Dr. Shull faults Ethicon for allegedly failing to take a "systematic approach" and to institute "proper randomized controlled trials." Ex. B to Doc. 4355, Prolift +M Report at 24-25; *see also id.* at 3 (asserting that Ethicon did not "properly test[] its products"), 25 (asserting that "Prolift was not adequately studied before it was launched" and referring to "inadequacies" in the studies), 26 (claiming that clinical data was not "sufficient"). There is no basis for Dr. Shull to criticize Ethicon's premarketing testing, when Dr. Shull has no credentials that would qualify him to provide an expert opinion as to what the standard of care required. Plaintiffs do not dispute this Court's observation that Dr. Shull has "no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices." *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D. W. Va. Apr. 28, 2015); *see also In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500765, at *5 (S.D.W. Va. Aug. 26, 2016); *Huskey v. Ethicon, Inc.*, 29 F. Supp.3d 691, 705 (S.D.W. Va. July 8, 2014); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D.W. Va. Apr. 28, 2015).

Consistent with those decisions and the Illinois federal district court's decision in *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *5 (N.D. Ill. June 22, 2017), the Court should exclude Dr. Shull's opinions on the basis that "Plaintiffs have not shown that Dr. Shull is qualified to testify regarding the standard of care for medical device testing," and that his opinions about the extent of testing "would merely address facts found in corporate documents." *Id.*

B. Adverse Event Reporting

In their response, Plaintiffs clarify that Dr. Shull does not intend to opine whether Dr. Shull's opinions about Ethicon's adverse event reporting complied with FDA regulations. They also assert that "Dr. Shull is not offering an opinion as to the *nature* or *quality* of the adverse event reporting that should have occurred; rather, he is stating that it did not occur." Doc. 4554, Pl's Resp. at 12. If this is the extent of Dr. Shull's intended testimony, then this is improper expert testimony as Plaintiffs' hope to misuse Dr. Shull to relay what Ethicon did or did not do. *See Walker*, 2017 WL 2992301, at *6 ("Dr. Shull cannot serve as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting").

C. Training

Regardless of whether Plaintiffs could show that Dr. Shull's training opinions are relevant, Plaintiffs have identified nothing in Dr. Shull's credentials that would demonstrate him to be competent about what the standard of care supposedly requires of a medical device manufacturer in terms of training physicians. Accordingly, the Court should preclude Dr. Shull from suggesting that Ethicon failed to provide adequate training to users of Prolift +M.

CONCLUSION

For the foregoing reasons and those set forth in Ethicon's initial brief, the Court should limit Dr. Shull's testimony in these cases.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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